



Part 15 Hearing

Promotion of FDA-Regulated Products Using the Internet and Social Media Tools

Testimony from
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The Social Web Effect

- Enabling people to informally organize around and discuss any topic or cause
- 80% of American adults participating in social media at some level
- Creating “connected, empowered consumers” who are starting to have more influence on brand messaging than corporations
- Future: Connected consumers will eventually exert even more control over brands by driving innovation through real-time feedback to companies



Source: Forrester Research's Consumer Technographics data.
Part of Forrester's [Groundswell](#) content.
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Why Pharma Must Participate

- Conversations about drugs, devices, and conditions are taking place in a permanent, trackable, interactive format and at an unprecedented level
 - 61% of American adults going online for healthcare information
 - 60% of this subset using social media as part of this effort
- Have a voice in conversations *that are already taking place about their brands.*
- Obligation to participate to ensure that accurate, transparent, high-quality information about their products is disseminated appropriately, and to correct false information where reasonable and possible.



Guideline Recommendations

- Larger than detailing how to remain compliant with the utilization of *specific* social media technologies,
 - Many of will change and evolve prior to the guidelines being issued
- Guiding how Pharma interacts with physicians, allied healthcare professionals and consumers within the social web and utilizes the vast amount of information available to them
- Four overarching principles to ensure that it remains relevant as new social technologies emerge:
 - Speed
 - Transparency
 - Responsibility
 - Reasonable Effort

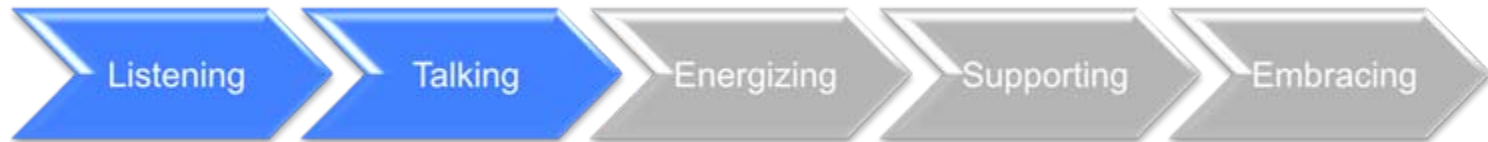


Speed

- Guidelines need to be implemented before 2010
- FDA needs to create a mechanism to keep pace with change in the space.
 - Advisory Committee
 - Experienced Interactive Strategy Lead – to advise on trends in Social Web and Technology
 - Medical Director – to advise on how the social web impacts professional and consumers' experiences as it relates to healthcare
 - Consumer Advocates
 - This committee would:
 - Hold regular meetings to review new technologies and *proactively* issue brief, regular guidances on how to appropriately use these technologies in compliance with FDA regulations
 - Implement a user-friendly site for disseminating these guidelines



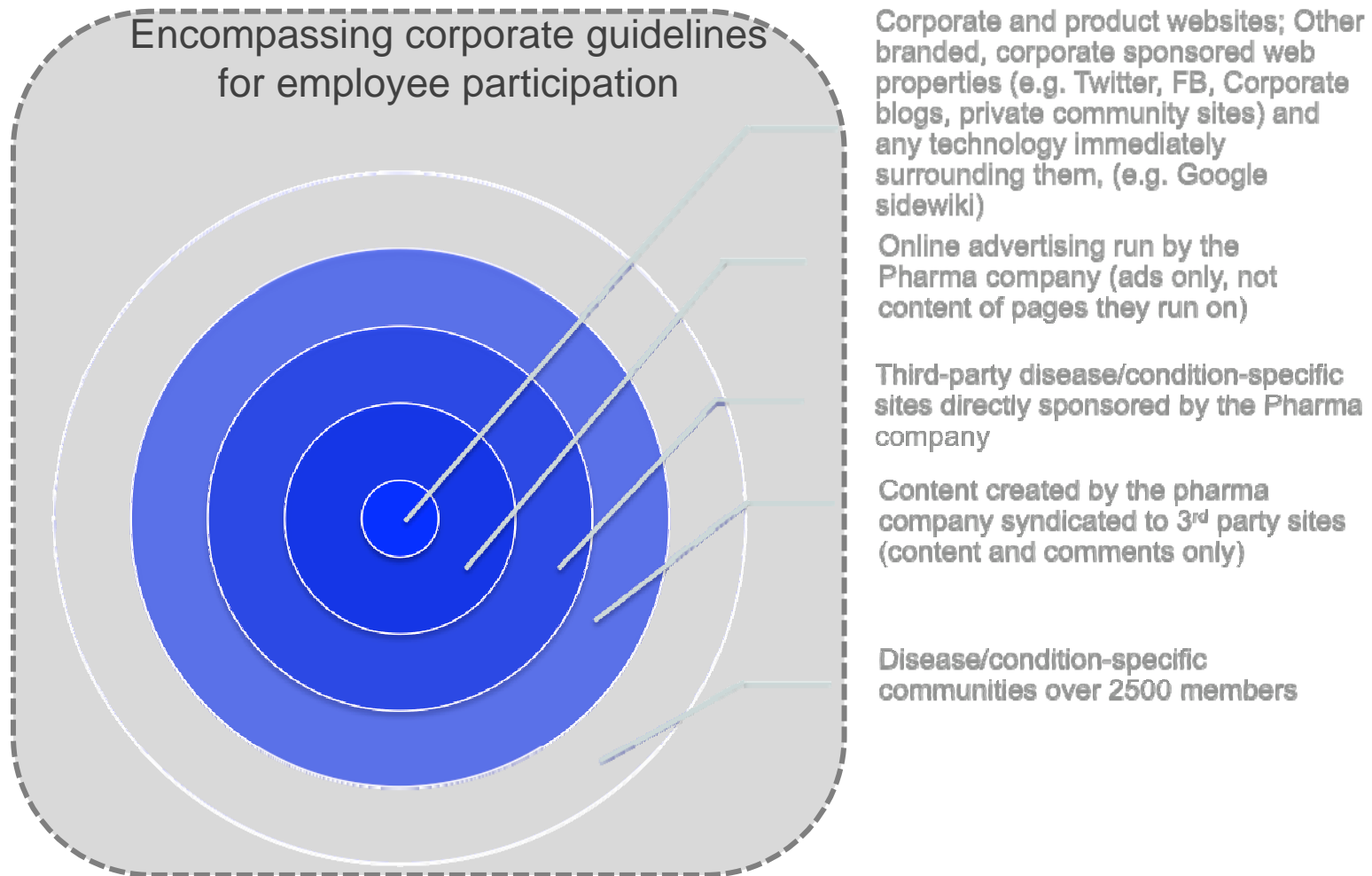
Responsibility



- Engagement at level of Listening and Talking
 - Require Pharma Companies to develop social media policies
 - compliant with FDA guidelines
 - include rules for engagement for brands and individuals.
 - Require social media monitoring role either on-staff or outsourced to an appropriately qualified agency.
 - Monitor social media
 - Identify when and where they should respond to brand and condition conversations to remain in compliance with FDA requirements
 - Stay abreast of the FDA committee's guidances on new social media technologies



Reasonable Effort within Responsibility Sphere





Sphere of Responsibility Details

Source	Information Responsibility
Corporate-controlled <ul style="list-style-type: none">• Corporate and product websites• Other branded, corporate sponsored web properties (e.g. Twitter, Facebook, Blogs, Podcasts, videos, private community sites)• Technologies immediately surrounding them (e.g. Google side-wiki)	<ul style="list-style-type: none">• Responsible for all information created by the company or its agents.<ul style="list-style-type: none">○ Accurate information that is in compliance with all FDA fair balance regulations regarding safety, efficacy, side effects and contraindications○ Presented in language and manner most appropriate for target audience○ One-click rule for fair balance information• Accountable for monitoring content posted by users to correct or remove inaccurate information, off-label use, etc.• Triage process for AE reporting
Online Ads (created by Pharma Company and it's agents)	<ul style="list-style-type: none">• Responsible for all information created by the company or its agents.<ul style="list-style-type: none">○ Accurate information that is in compliance with all FDA fair balance regulations regarding safety, efficacy, side effects and contraindications○ Presented in language and manner most appropriate for target audience○ One-click rule for fair balance information• Not accountable for content on properties where ads are run unless they re targeting social media communities which cater to consumers suffering from or prescribers treating that condition.• In the case of advertising on targeted social media sites, they should place additional, reasonable effort on monitoring these sites to respond to: adverse events; off-label prescribing; and incorrect information



Sphere of Responsibility Details

Source	Information Responsibility
Third-party disease/condition-specific sites directly sponsored by the Pharma company	<ul style="list-style-type: none">• full disclosure noting that they are the sponsor• remain true to the mission of the site• Responsible for all information created by the company or its agents.<ul style="list-style-type: none">○ Accurate information that is in compliance with all FDA fair balance regulations regarding safety, efficacy, side effects and contraindications○ Presented in language and manner most appropriate for target audience○ One-click rule for fair balance information• If the sites contain a dialog/social media component, the pharma company, even if they engage a designated agent, is responsible for monitoring content for incorrect, inaccurate or off-label information and responding to it.• Triage process for AE reporting
Syndicated Content <ul style="list-style-type: none">• Content developed by Pharma Company and syndicated to third-party sites• Content not created by the Pharma Company on the 3rd party sites	<ul style="list-style-type: none">• Responsible for all information created by the company or its agents.<ul style="list-style-type: none">○ Accurate information that is in compliance with all FDA fair balance regulations regarding safety, efficacy, side effects and contraindications○ Presented in language and manner most appropriate for target audience○ One-click rule for fair balance information• Responsibility does <i>not</i> extend to surrounding content that is published by the third-party and not sponsored by the pharma company, except for comments on the pharma content.• Engage in reasonable efforts to occasionally monitor the 3rd party sites for issues



Sphere of Responsibility Details

Source	Information Responsibility
Large Disease/Condition-specific Community Sites (>2500 people) – Non-pharma company sponsored consumer or professional sites	<ul style="list-style-type: none">• Recommendation, but <i>not a requirement</i>, to occasionally monitor for:<ul style="list-style-type: none">◦ Consumer/Professional insights◦ Early warning on safety or efficacy issues• Triage process for AE reporting



Transparency

- Pharma companies *must* be transparent in every promotional they engage in regardless of the media channel.
- Required to disclose when they are participating in any communication about their drug or device whether it is a direct promotional effort or a disease-awareness initiative.
- Aligns with other rulings social media space as the FTC has recently ruled that bloggers must disclose when they are writing about a particular product for which any type of compensation (product or monetary) has been received.



Why the FDA Must Act Now

- At a crossroads in the pharma industry
- Social media offers
 - A tremendous opportunity to rebuild trust with consumers and healthcare professionals if used to share quality, accurate information
 - A better way to engage healthcare providers and gain actionable insight
 - A way to gain consumer and product insight
 - An early warning system for potential product problems
 - An effective tool for increasing regimen persistence and compliance
- Users are already online looking for this information.
- Pharma companies have the opportunity to step up and ensure they are providing the most accurate, reliable source of information for their consumers and professionals rather than allowing someone else to do so.
- *Nature abhors a vacuum; if Pharma doesn't do this, others will*